UNITED STATES DISTRICT COURT

DISTRICT OF RHODE ISLAND

DONNA DELOREY, an individual; PAUL DELOREY, an individual, Plaintiffs, vs. ABBOTT LABORATORIES, a corporation, ALERE INC., a corporation; ALERE HOME MONITORING INC., a corporation; ALERE SAN DIEGO INC., a corporation; QUALITY ASSURED SERVICES, INC., a corporation, , and DOES 1 through 100, Defendants.	Case No.: **COMPLAINT FOR DAMAGES** 1. Fraud 2. Negligence 3. Negligence Per Se 4. Breach of Warranty 5. Strict Liability – Failure to Warn 6. Strict Liability – Manufacturing & Design 7. Unfair Competition Laws 8. Loss of Consortium **JURY TRIAL DEMANDED**

1. Come now, DONNA DELOREY AND PAUL DELOREY ("Plaintiffs") who allege:

2. This action for product liability and fraud is against ABBOTT LABORATORIES, ("Abbott"), and its wholly owned subsidiary ALERE, INC., ALERE SAN DIEGO INC., ALERE HOME MONITORING INC., and QUALITY ASSURED SERVICES, INC., ("the Alere defendants"), who are the designers, manufacturers, promoters, distributors and/or sellers of the "INRatio PT/INR Monitors," "INRatio PT/INR Test Strips," "INRatio2 PT/INR Monitors" and "INRatio2 PT/INR Test Strips" (the "INRatio Products").

3. For patients taking anticoagulation medications ("blood-thinners"), the ability to monitor and test their blood-clotting times and adjust their dosages accordingly is essential. Failure to take the appropriate dosage of blood-thinners can result in serious bodily injuries and death. Defendants' INRatio Products are electronic testing devices designed (at least in theory) to help patients who have been prescribed blood-thinners monitor their blood-clotting times, to ensure they are receiving the proper dosage.

4. Unbeknownst to consumers, almost immediately after the INRatio Products became available to the public, Defendants learned that the INRatio Products produced erroneous results. Defendants received numerous complaints from users and multiple warning letters from the Food and Drug Administration ("FDA"), notifying them that the results produced by the INRatio Products differed from those produced by independent laboratories. Nevertheless, Defendants withheld material information from the public and continued selling the INRatio Products unabated, marketing and advertising them to patients and the medical community as an INR monitor which was "accurate," "convenient," "effective," "reliable," "optimal" and "safe." Contrary to Defendants' representations, the INRatio Products were not international normalized ratio monitors, nor were they "accurate," "convenient," "effective," "reliable," "optimal" or "safe."

5. Believing the results produced by a testing product like the INRatio Products are accurate, as any reasonable patient would, patients of the INRatio Products (as well as patients' respective medical providers), relied on the erroneous results produced by the INRatio Products and improperly adjusted their blood-thinner dosages, increasing the risk and likelihood of serious bodily injury or death. Because of Defendants' defective INRatio Products and fraud, thousands of vulnerable and unsuspecting patients, including Plaintiffs, have been seriously and permanently injured.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiffs seeks damages in excess of $75,000, exclusive of interest and costs.

7. This Court has personal jurisdiction over Abbott insofar as Abbott is authorized and licensed to conduct business in the State of Rhode Island, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this district, and regularly avails itself of the benefits of this judicial district.

8. This Court has personal jurisdiction over the Alere defendants insofar as said

defendants are authorized and licensed to conduct business in the State of Rhode Island, maintain and carry on systematic and continuous contacts in this judicial district, regularly transact business within this district, and regularly avail themselves of the benefits of this judicial district.

9. Additionally, all defendants caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and servives rendered in this judicial district.

PARTIES

10. Plaintiffs, DONNA DELOREY and PAUL DELOREY are residents of Charlestown, Rhode Island and citizens of the State of Rhode Island.

11. Defendant, ABBOTT LABORATORIES, is an Illinois corporation with its principle place of business in Abbott Park, Illinois. Upon information and belief, Abbott Laboratories is the successor in interest to the Alere defendants by and through an Agreement and Plan of Merger with Alere, Inc., which provided for the merger of a newly formed wholly owned subsidiary of Abbott with and into Alere, Inc., with Alere Inc., surviving the merger as a wholly owned subsidiary of Abbott.

12. Defendant, ALERE, INC., at all relevant times, was a Delaware corporation with its principle place of business in Waltham, Massachusetts. Alere, Inc., independently and through its subsidiaries Defendant Alere San Diego, Inc., Defendant Alere Home Monitoring, Inc., and Defendant Quality Assured Services, Inc., manufactured, marketed, and sold medical diagnostic testing products (including the INRatio Products) for professionals, patients and consumers around the country.

13. Defendant ALERE SAN DIEGO, INC., at all relevant times, was a Delaware corporation doing business nationwide with its principle place of business in San Diego, California. Alere San Diego, Inc., at all relevant times, was a wholly owned and controlled

subsidiary of Alere, Inc. Defendant Alere San Diego, Inc. manufactured, marketed and sold diagnostic testing products, including the INRatio Products.

14. Defendant ALERE HOME MONITORING, INC., at all relevant times, was a Delaware corporation doing business nationwide with its principle place of business in Livermore, California. At all relevant times, it was a wholly owned and controlled subsidiary of Defendant Alere, Inc. who assisted patients, in Rhode Island and nationwide, in acquiring the INRatio Products and provides physicians with the necessary tools to allow them to integrate the patient self-testing undertaken with the INRatio Products into their practices.

15. The Alere defendants designed, manufactured, promoted, sold and distributed the INRatio products at issue. In 2015, Alere, Inc. reported revenue of $2.4 billion and generated over $1.3 billion in gross profits.

16. The INRatio system was originally manufactured by HemoSense, Inc. (HemoSense), a corporation with its principle place of business in San Jose, California. HemoSense received FDA approval for the INRatio PT/INR Monitors and INRatio PT/INR Test Strips in 2002, and commercial sales began in 2003. In August of 2007, HemoSense was purchased by Alere, Inc. (then known as Inverness Medical Innovations, Inc.). In 2008, HemoSense transferred its operations to Alere, Inc.'s facility in San Diego, California. HemoSense's operations then merged into the Alere San Diego corporate entity.

17. The true names and capacities, whether individual, corporate, associate, or otherwise, of the defendants named herein, under the fictitious names of DOES 1 through 100, inclusive, are either unknown to Plaintiffs or, alternatively, the fact of their liability is unknown by Plaintiffs, who, therefore, sue said defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiffs for the acts and omissions alleged herein below, and the resulting injuries to Plaintiffs, and damages

sustained by the Plaintiffs. Plaintiffs may amend this Complaint to allege the true names and capacities of said defendants when the same has been ascertained or when the fact of their respective liability has been established.

18. Defendants Alere, Inc., Alere Home Monitoring, Inc., Alere San Diego, Inc. and DOES 1 through 100 are collectively referred to herein as "Alere" or "Defendants."

19. At all relevant times, Defendants' officers and directors authorized, directed, ratified, and/or participated in the conduct alleged herein when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of their tortious conduct and concealment and thereby actively participated in tortious conduct, which resulted in the physical injuries described herein.

20. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants, and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants would permit an abuse of the corporate privilege, would sanction fraud, and would promote injustice.

21. Plaintiffs are informed and believe, and based thereon allege, that at all material times herein, Defendants and each of them, and their owners, aggregates, corporate associates and partners, were the agent, servant, employee, assignee, permissive user, successor in interest or joint venture of each other, and were acting within the time, purpose, scope, and course of said agency, service, or employment, and with the express or implied knowledge, permission, and consent of the other Defendants, and ratified and approved the acts of the other Defendants

22. Whenever in this Complaint reference is made to any act, deed, or conduct of Defendants committed in connection with wrongful acts alleged, the allegation means that Defendants engaged in the act, deed, or conduct by or through one or more of their officers,

directors, agents, employees or representatives, each of whom was actively engaged in the management, direction, control or transaction of the ordinary business and affairs of Defendants

FACTUAL ALLEGATIONS

A. The International Normalized Ratio ("INR")

23. The International Normalized Ratio ("INR") is a standardized metric used to determine the relative speed at which blood clots in a patient's body. A patient's INR is calculated by comparing a patient's prothrombin time (the speed at which the patient's blood clots) against the normal mean prothrombin time (the average speed for blood clotting in the general population). The resulting contrast between a patient's prothrombin time and the normal mean prothrombin time is the patient's INR. For example, a patient whose blood-clotting time is double that of the average person's blood-clotting time will have an INR of 2.0.

24. The INR is a measurement for doctors and patients to monitor the blood-clotting speed for patients who have been prescribed anticoagulants ("blood thinners") for certain medical conditions, including but not limited to blood clots, or following the surgical implantation of medical devices, including but not limited to heart valves. Doctors can use the INR measurement to determine whether a patient should increase or decrease his/her dosage of blood thinners.

25. It is essential for doctors and patients to be able to regularly measure a patient's INR and alter the blood-thinner dosage accordingly due to the serious health risks associated with both high and low blood-clotting times. High INRs (indicating a relatively slow blood-clotting time) can lead to excessive bleeding[1], and generally indicates too high a dosage of blood-thinners. Meanwhile, a low INR (indicating a relatively quick blood-clotting time) can lead to strokes, and generally indicates too low a dose of blood-thinners.

[1] For example, it has been reported that in certain circumstances, the risk of intracranial hemorrhage increases approximately 2-fold for every 1unit rise in INR.

In both cases, the consequences of having an irregular INR can lead to serious injury and death. For these reasons, many patients who take blood thinners constantly monitor their INRs to ensure they are receiving the proper dosage.

B. INRatio "INR Monitoring" System

26. Defendants developed and manufactured the "INRatio monitor," a point-of-care INR monitor that was designed to help patients who have been prescribed blood-thinners, in particular warfarin, to monitor their INRs at home. Much like those devices used by diabetic patients to monitor their blood-sugar levels, the INRatio monitor worked by having patients insert a blood sample (via an INRatio test strip) into an electronic testing device. The testing device, after analyzing the blood sample, would then reveal the INR value via an electronic display.

27. The "INRatio monitor," paired with the INRatio test strips, was known as the "INRatio testing kit."

28. Distribution of the INRatio testing kit for home use and commercial sales began in 2003.

29. Eventually, the INRatio testing kit gave way to the "INRatio2" testing kit. The INRatio2 testing kit operated similarly to its predecessor, pairing an electronic monitor with corresponding test strips.

C. Defendants' Knowledge of the INRatio Products' Defective Qualities

30. Almost immediately after Defendants made the INRatio Products available to the public, Defendants began receiving numerous complaints about the INRatio Products' efficacy and accuracy. In particular, some consumers found that the INR results they were getting when using the INRatio Products differed from the results they obtained when they sent blood from the same samples to independent labs for testing. The deviations between the INRatio Products' test results and those of independent labs were "clinically significant." In most cases, the INRatio Products produced INR results that turned out to be

incorrectly low, although in numerous other instances, the INRatio Products produced results that were incorrectly high.

31. In 2007, a team of doctors in London conducted a study that tested five point-of-care INR testing devices, the INRatio Products among them, for quality and reliability (the "London study"). The doctors took blood samples from patients and determined the patients' INR values using the five point-of-care testing devices. The doctors then took those same blood samples and sent them to an outside laboratory to obtain secondary INR results. The study determined that among the five point-of-care devices tested, the INRatio Products performed the worst, with results that deviated most significantly from the results obtained through the outside laboratory.

D. Defendants' Unlawful Failure to Properly Report and Respond to Adverse Events

32. Upon information and belief, between 2002 and 2014, Defendants received over 18,000 complaints concerning malfunctions with the INRatio Products, with three deaths reported.

33. In May of 2005, following the receipt of numerous complaints concerning Defendants' INRatio systems, the FDA conducted an inspection of Defendants' (then) San Jose operations facility.

34. Following the inspection, the FDA sent a warning letter ("2005 Warning Letter") to Defendants admonishing them for their failure to file adverse event reports (also known as MDR reports).[2] The letter further labeled the INRatio PT/INR Monitors and

[2] 21 CFR § 803.50(a) requires medical device manufacturers to file Medical Device Reporting reports ("MDR reports") to the FDA within 30 days after they "receive or become aware of information, from any source, that reasonably suggests that a device [they] market: (1) [m]ay have caused or contributed to a death or serious injury; or (2) [h]as malfunctioned and this device or a similar device that [they] market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Additionally, 21 U.S.C. § 360i(a)(1) requires device manufacturers to report to the FDA, in compliance with 21 CFR §803, when the manufacturer receives or otherwise becomes aware of information that reasonably suggests its product either caused a death or serious injury, or malfunctioned in a way such that a similar device would be likely to cause death or serious injury were

INRatio PT/INR Test Strips as "misbranded" due to "a serious regulatory problem involving INRatio Test Strips and INRatio Test Meters."

35. The letter stated, "Our record indicates your firm had information indicating that INRatio devices were generating clinically significant erroneous values." More importantly, the letter pointed out that, "[i]f the INR is too low, a patient will be prone to blood clots or strokes. If the INR is too high, a patient will be prone to excessive bleeding. Therefore, both high and low test results *have the potential to cause or contribute to a death or serious injury* because they may result in erroneous dosing and thus improper control of [clotting]."

36. The letter went on to cite specific complaints that had been received by Defendants wherein the INRatio "provided discrepant results [compared] to lab results," and "[t]his indicates that your device failed to meet its performance specifications or otherwise perform as intended, and therefore malfunctioned." Further, "[a]ll of these erroneous readings were clinically significant and were thus likely to lead to incorrect application of [blood-thinner] therapy, with the likely health consequences already noted.

37. The letter concluded that the Defendants had failed to comply with the Medical Device Reporting regulations because they did not file MDR reports within 30 days of receiving the above-mentioned complaints. The letter further concluded that Defendants' internal MDR procedure was inconsistent with all the terms of 21 CFR § 803. In particular, Defendants' internal MDR policy only treated complaints as reportable if an investigation determined that "the device *has* caused or contributed to a death or serious injury." Meanwhile, 21 CFR § 803.50 requires manufacturers to submit MDRs when a device "*may have* caused or contributed to a death." In other words, the FDA concluded Defendants' failure to submit MDRs to the FDA was the result of an unlawful systemic policy.

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the malfunction to recur. Further, under 21 U.S.C. § 352, any failure to comply with 21 CFR § 803.50(a) and 21 U.S.C. § 360i (a)(1) will result in the device being deemed "misbranded."

38. From May 15, 2006 through July 13, 2006, investigators from the FDA conducted another inspection of Defendants' (then) San Jose facility.

39. On November 29, 2006, the FDA sent Defendants another warning letter ("2006 Warning Letter") faulting Defendants for numerous failures to comply with statutory regulations.

40. The 2006 warning letter admonished Defendants, *inter alia*, for: (1) failing to investigate complaints involving possible failures of devices to meet any of its specifications; (2) failing to promptly review, evaluate and investigate complaints representing events that are MDR reportable; and (3) failing to file MDRs with the FDA.

41. Despite the above admonishments from the FDA, and despite thousands of complaints received concerning malfunctions that either caused or were likely to have caused serious injuries or death (including three malfunctions which did, in fact, result in deaths), Defendants failed to properly submit MDR reports to the FDA, failed to advise consumers, Plaintiffs and the medical community of the FDA's admonishments and the defects plaguing the INRatio Products, and continued selling the INRatio Products unabated, at all times falsely representing to consumers, Plaintiffs, and their respective medical providers that the device was an INR monitor, which was safe, accurate, reliable and effective, when such representations were, in fact, false.

E. Defendants' Misrepresentations and Omissions Regarding the INRatio and INRatio2 Testing Kits

42. Defendants misrepresented that the INRatio testing kit was "accurate," "convenient," "effective," "reliable," "optimal" and "safe" in its marketing, advertising and promotional materials. Defendants made further misrepresentations to consumers and healthcare professionals by naming the monitor the "INRatio Monitor" and placing the words "INRatio Monitor" on the packaging, leading reasonable consumers and healthcare professionals to believe that the product safely, effectively and accurately monitored the users' INRs, when in fact they produced false and erroneous results. Contrary to

Defendants' representations, the INR Products were not INRatio Monitors because rather than "monitor" consumers' International Normalized Ratio, the INRatio Products produced erroneous, unreliable results and effectively did not monitor anything.

43. Defendants made further misrepresentations to consumers and healthcare professionals by omitting material information from the packaging and marketing materials on the INRatio testing kit, in particular, by failing to disclose that the INRatio Products produced false and erroneous results.

44. Consistent with its predecessor, Defendants misrepresented to consumers and healthcare professionals in its marketing, advertising and promotional materials that the INRatio2 testing kit was "accurate," "convenient," "effective," "reliable," "optimal," and "safe."

45. Defendants made further misrepresentations to consumers and healthcare professionals by naming the monitor the "INRatio2 Monitor" and placing the words "INRatio2 Monitor" on the packaging, leading reasonable consumers and healthcare professionals to believe that the products safely, effectively, and accurately monitored the users' INRs, when, in fact, rather than monitor consumers' International Normalized Ratio, they produced false and misleading results.

46. Defendants made further misrepresentations to consumers and healthcare professionals by omitting material information from the packaging and marketing materials of the INRatio Products, in particular, by failing to disclose that the INRatio Products produced false and misleading results. In fact, the only reason a reasonable consumer would use the INRatio 2 testing kit is to obtain accurate, reliable, and safe results. A testing product that does not provide reliable results is worthless.

47. A true and correct copy of some of Defendants' representations concerning the INRatio2 testing kit is as follows:

48. Further, by falsely and misleadingly representing to consumers and healthcare professionals that the INRatio Products were "accurate," "convenient," "effective," "reliable," "optimal," and "safe" in their marketing, advertising and promotional materials, Defendants made a partial representation while suppressing material facts. In particular, Defendants suppressed what they had known for years: the INRatio Products produce false and erroneous results.

49. Further, by falsely and misleadingly representing to healthcare professionals and consumers that the INRatio Products were "accurate," "convenient," "effective," "reliable," "optimal," and "safe" in their marketing, advertising and promotional materials, Defendants actively concealed material information from healthcare professionals and consumers. In particular, that the INRatio Products produced false and erroneous results.

50. Defendants further misled consumers and healthcare professionals by withholding information exclusively known to them. In particular, Defendants knew the

INRatio Products contained specific defects, including, but not limited to, defective software and other defects that could be remedied with enhancements to the software. Defendants also knew that these defects were the cause of the INRatio Products' propensity for producing false and erroneous results.

51. In fact, unbeknownst to consumers and healthcare professionals, Defendants were conducting undisclosed studies to determine the effectiveness of their software enhancements. Defendants suppressed and actively concealed the defects and the studies, while simultaneously misrepresenting the INRatio Products to be International Normalized Ratio "monitors" which were "accurate," "convenient," "effective," "reliable," "optimal," and "safe," when in fact, the INRatio Products were anything but.

52. Additionally, by falsely and misleadingly representing to consumers and healthcare professionals that the INRatio Products were "accurate," "convenient," "effective," "reliable," "optimal," and "safe" in their marketing, advertising, and promotional materials while suppressing and actively concealing material information (including information exclusively known to Defendants), Defendants prevented healthcare professionals and consumers from making informed decisions regarding the use of the INRatio Products. By preventing healthcare professionals from making informed decisions regarding the use of the INRatio Products, Defendants altered and affected prescribing physicians' decisions concerning their patients' use of the products.

53. Had Defendants disclosed the above material information, that the INRatio Products contained specific defects that produced false and erroneous results and that Defendants were fully aware of these defects and communicating with the FDA about these defects and attempting to remedy them with software enhancements and studies, healthcare providers would have been made aware of the defects and would not have prescribed the INRatio Products to consumers. Similarly, consumers would have been made aware of the defects by consulting with their informed healthcare providers and would not have purchased or used the INRatio Products. Further, had Defendants disclosed that the INRatio

Products contained specific defects that produced false and erroneous results, consumers, including those who did not receive prescriptions, would have been made aware of the defects and would not have purchased or used the INRatio Products.

F. Defendants' Class 1 Recalls of the INRatio and INRatio2 Testing Kits

54. On April 16, 2014, Defendants issued a voluntary recall notice to healthcare professionals for the INRatio2 test strips, citing the disparity between INR results obtained with the INRatio2 system versus significantly higher INR results when re-testing was performed by an independent laboratory. Defendants' recall notice requested that customers immediately cease using the INRatio2 PT/INR test strips and instead use alternate methods to perform INR testing, including substituting INRatio PT/INR test strips for the defective INRatio2 PT/INR test strips.

55. By singling out the INRatio2 PT/INR test strips in the April 16, 2014 recall notice, Defendants made a partial representation while suppressing material facts. In particular, the April 16, 2014 recall notice failed to disclose what Defendants had known for years: the defective qualities of the INRatio Products were not limited to the INRatio2 PT/INR test strips. In fact, at the time Defendants issued the April 16, 2014 recall notice, they well knew that the INRatio PT/INR *Monitors*, the INRatio2 PT/INR *Monitors* and the INRatio PT/INR test strips produced false and erroneous results.

56. By directing users to substitute the INRatio PT/INR test strips for the defective INRatio2 PT/INR test strips, Defendants falsely and misleadingly represented to healthcare professionals and consumers that the INRatio PT/INR test strips performed properly, when in fact they caused false and erroneous results.

57. In the April 16, 2014 recall notice, Defendants also failed to disclose that the INRatio Products contained specific defects (including but not limited to defective software) that produced false and erroneous results.

58. Further, by falsely and misleadingly representing to healthcare professionals and consumers in the April 16, 2014 recall notice that the cause of the INRatio Products'

defective qualities was limited to the INRatio2 PT/INR test strips, Defendants prevented healthcare professionals and consumers from making informed decisions regarding the use of the INRatio Products. Additionally, by falsely and misleadingly representing to healthcare professionals and consumers that the cause of the INRatio Products' defective qualities was limited to the INRatio2 PT/INR test strips, Defendants altered and affected prescribing physicians' decisions concerning their patients' use of the products.

59. Further, by falsely and misleadingly representing to healthcare professionals and consumers in the April 16, 2014 recall notice that the cause of the INRatio Products' defective qualities was limited to the INRatio2 PT/INR test strips, Defendants suppressed and actively concealed material information, known exclusively by Defendants, from healthcare professionals and consumers.

60. Making matters worse, numerous patients, including those who had received prescriptions for the INRatio Products, never received the April 16, 2014 recall notice.

61. The FDA classified Defendants' April 16, 2014 recall notice as a "Class 1" recall because it involved the use of products that would cause serious adverse health consequences or death.

62. On December 5, 2014, Defendants issued a "voluntary" recall letter to customers for the INRatio PT/INR Monitor, INRatio2 PT/INR Monitor, and the INRatio PT/INR Test Strips. The letter stated, "[i]n certain cases an INRatio® PT/INR Testing kit may provide an INR result that is significantly lower than a result obtained using a laboratory INR system." However, the December 5, 2014 recall notice failed to state that *the INRatio Products themselves* were defective. Instead, the notice falsely stated that the false and erroneous results "can arise if [users] have certain medical conditions." The notice also blamed the false and erroneous results on the users' failure to "carefully follow the instructions for performing the test."

63. Making matters worse, the notice did not instruct all users to cease altogether using the INRatio Products. Instead, the notice instructed users to contact their doctors to

determine if any of the relevant medical conditions applied to them. The notice also instructed users to take certain precautions to reduce the risk of erroneous results associated with the users' alleged and asserted failure to carefully follow the instructions.

64. By issuing the December 5, 2014 recall notice that falsely and misleadingly blamed the erroneous results on "certain medical conditions" and the failure to "carefully follow the instructions", Defendants made only a partial representation of the true defects of the product while suppressing additional crucial, material facts. In particular, the December 5, 2014 recall notice failed to disclose what Defendants had known for years: the defective qualities of the INRatio Products were not limited to certain medical conditions of users, or failures to follow instructions carefully. In fact, at the time the December 5, 2014 recall notice issued, Defendants knew that all of the INRatio Products produced false and erroneous results, irrespective of the users' medical conditions.

65. In the December 5, 2014 recall notice, Defendants also failed to disclose that the INRatio Products contained specific defects (including, but not limited to, defective software) that produced false and erroneous results and that Defendants were communicating with the FDA about these defects and attempting to remedy them with software enhancements and studies.

66. Further, by falsely and misleadingly representing to healthcare professionals and consumers in the December 5, 2014 recall notice that the cause of the INRatio Products' defective qualities was limited to "certain medical conditions" and the failure to "carefully follow the instructions," Defendants prevented healthcare professionals and consumers from making informed decisions regarding the use of the INRatio Products. Additionally, by falsely and misleadingly representing to healthcare professionals and consumers that the cause of the INRatio Products' defective qualities was limited to the "certain medical conditions" and the failure to "carefully follow the instructions," Defendants altered and affected prescribing physicians' decisions concerning their patients' use of the products.

67. Further, by falsely and misleadingly representing to healthcare professionals and consumers that the cause of the INRatio Products' defective qualities was limited to "certain medical conditions" and the failure to "carefully follow the instructions" in the December 5, 2014 recall notice, Defendants suppressed and actively concealed material information from healthcare professionals and consumers.

68. Making matters worse, numerous patients, including those who had received prescriptions for the INRatio Products, never received the December 5, 2014 recall notice.

69. The FDA classified Defendants' December 5, 2014 recall notice as a "Class 1" recall because it involved the use of products that would cause serious adverse health consequences or death.

70. Finally, on July 11, 2016, Defendants issued a recall notice withdrawing the INRatio Products from the market. The recall notice stated that Defendants had spent at least two years developing software enhancements to address the INRatio Products' defective qualities, but the FDA notified Defendants it believed the Defendants' studies did not adequately demonstrate the effectiveness of the software modification. The recall notice also stated the FDA "advised" (i.e., required) Defendants to remove the INRatio Products from the market.

71. Prior to the July 11, 2016 recall notice, Defendants never disclosed to healthcare providers or consumers that the INRatio Products contained specific defects, including but not limited to defective software and other specific defects which could be remedied with enhancements to the software. Defendants also never previously disclosed that these defects were the cause of the INRatio Products' propensity for producing false and erroneous results or that the Defendants had been conducting studies to determine the effectiveness of their software enhancements.

72. The July 11, 2016 recall notice made no mention of "certain medical conditions" or any failure to "carefully follow the instructions." Instead, Defendants abandoned those false and misleading claims and admitted what they had known since 2005:

the INRatio Products simply do not work.

G. The ROCKET AF Trial[3]

73. The damage caused by the INRatio Products' failures, Defendants' unlawful refusal to acknowledge or address those failures, and Defendants' continued manufacturing, marketing and selling of a dangerously defective product to unsuspecting consumers, extended beyond the harm suffered by individual users.

74. In September of 2011, the New England Journal of Medicine published a study later known as the "ROCKET AF trial." The purpose of the ROCKET AF trial was to compare the most commonly prescribed anticoagulant, warfarin, to a newer drug called rivaroxaban (hereinafter by its trade name, "Xarelto") to determine which drug was more statistically effective in preventing strokes and embolisms.

75. As part of the methodology, some of the patient-participants were prescribed Xarelto at a fixed dose (the "Xarelto group"), while others were prescribed warfarin at a non-fixed dose (the "warfarin group"). The warfarin group adjusted their dosage based on their INR values, which they were instructed to keep between 2.0 and 3.0. In other words, the warfarin group would constantly monitor their INRs and take whatever dosage of warfarin was necessary to keep their INR values within the appropriate range.

76. The study determined Xarelto to be "noninferior" to warfarin, and the findings ultimately led to Xarelto's FDA approval.

77. Following the April 16, 2014 and December 5, 2014 recalls of the INRatio Products, it was revealed that the warfarin group in the ROCKET AF study had used the INRatio Products to monitor their INR values and adjust their dosages accordingly.

78. The revelation that the results of the ROCKET AF study were premised, in part, on data collected from individuals using the INRatio Products has called the entire

[3] ROCKET AF being an acronym for "**R**ivaroxaban **O**nce Daily Oral Direct Factor Xa Inhibition **C**ompared with Vitamin **K** Antagonism for Prevention of Stroke and **E**mbolism **T**rial in **A**trial **F**ibrillation.

study into question. A comparison of blood samples from over 5,000 of the ROCKET AF participants revealed that the INR data collected using the INRatio Products differed from the test results obtained from a third-party laboratory. Johnson & Johnson, makers of Xarelto, turned over the data from the ROCKET AF study to Alere.

79. According to Sidney Wolfe, M.D., founder of the Public Citizen Health Research Group, and F.R. Rosendaal, M.D., Ph.D., chair of the Department of Clinical Epidemiology at Lieden University Medical Center, Lieden University, in evaluating the ROCKET AF study and the subsequent revelations relating to the INRatio test results, "[n]othing could more adversely impact the validity of monitoring warfarin's blood-thinning effectiveness . . . than false readings -- whether too high or too low -- generated by the testing device used to monitor the degree of blood thinning (the INR)."

TOLLING OF THE STATUE OF LIMITATIONS AND DISCOVERY RULE

80. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment of the information and their misleading actions, as alleged herein. Without any fault or lack of diligence on their part, plaintiffs were kept ignorant of critical information required for the prosecution of their claims. Plaintiffs could not reasonably have discovered the true nature of the Defendants' defective and fraudulently promoted INRatio Products.

81. Defendants knowingly, affirmatively, and actively concealed the true character, quality, and nature of their INRatio Products. In particular, Defendants deliberately flaunted the Title 21 regulations requiring them to report the INRatio Products serious and life-threatening malfunctions to the FDA. Plaintiffs reasonably relied upon Defendants' knowing, affirmative, and active concealment of the truth about the INRatio Products. Based on the foregoing, Defendants are estopped from relying on any statutes of limitation as a defense in this action.

82. Defendants' failure to document or follow up on the known defects of its products, and concealment of known defects, serious increased risks, dangers, and

complications, constitutes fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiffs herein.

83. Defendants are estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of their INRatio Products, actively and intentionally concealed the defects, suppressed reports and adverse information, failed to satisfy FDA requirements, failed to satisfy FDA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and consumers, including the Plaintiffs herein.

84. Instead, Defendants continued to represent the INRatio Products as safe, accurate, and reliable, yet all the while they knew that this was absolutely false and untrue.

85. Defendants did the above acts, which were and are illegal under state and federal law, to encourage medical providers and Plaintiffs, to prescribe and use, respectively, their INRatio Products.

86. At all relevant times, Defendants were under a continuing duty under state and federal law to disclose the true character, quality, and nature of the increased risks associated with their INRatio Products.

87. Because of Defendants' concealment of the true character, quality, and nature of their products, they are estopped from relying on any statute of limitations defense.

88. Defendants furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects of their INRatio Products, and continued and systematic failure to disclose and/or cover-up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

89. Defendants' acts and omissions, before, during and/or after the act causing Plaintiffs' injury prevented Plaintiffs from discovering the injury or cause thereof until recently.

90. The first time that Plaintiffs knew or could have reasonably known that their respective injuries were caused by the wrongful conduct of a third party was when, in July

2016, Defendants, following mandatory instructions by the FDA, issued a recall of the Alere INRatio Products and *removed* all said products from the market. This was the first time that Defendants informed the public and the medical community that the Alere INRatio Products contained fundamental software defects and were defective for all conditions and uses, and that --- contrary to previous statements --- the erroneous readings were *not* caused by user error but, instead, resulted from intrinsically defective devices.

91. Defendants' conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the health consequences to or the rights and safety of the Plaintiffs.

92. Plaintiff Donna Delorey suffers from a medical condition that requires her to take warfarin (trade name "Coumadin"). As a result, Mrs. Delorey needs to monitor her INR values carefully.

93. In approximately 2009, Mrs. Delorey began monitoring her blood clotting times using the Alere INRatio 2 Monitor. Mrs. Delorey reported her readings to her primary care physician. On or around December 2014, Mrs. Delorey suffered aortic valve complications and anemia.

94. Plaintiff relied on Defendants' misrepresentation that one of the INRatio products was an "INRatio Monitor," which caused Plaintiff to believe the INRatio Products would allow her to safely and accurately monitor her INR values. Were it not for this misrepresentation, Plaintiff would not have purchased and/or used the INRatio Products. Further, had Plaintiff known that Defendants were omitting, suppressing and actively concealing material information, in particular, that Defendants knew their INRatio Products produced erroneous INR results, Plaintiff would not have used the INRatio Products. Had Defendants disclosed the above material information, Plaintiff would not have used the INRatio Products. Had Defendants disclosed that the INRatio Products contained specific defects that produced false and erroneous results, Plaintiff would not have used the products. Had Defendants timely removed the Alere INRatio Products from the market,

Plaintiff would not have been able to use the defective devices and would not have been exposed to the risks and injuries caused by the defective devices.

95. Upon information and belief, Mrs. Delorey's injuries occurred because of a defect in the Alere INRatio Products, which returned significantly inaccurate INR results, which in turn prevented her medical providers from prescribing a safe and effective dosage of Coumadin in a timely manner and caused her to suffer the injuries described herein.

96. Plaintiff Paul Delorey is the husband of Plaintiff Donna Delorey and brings a claim for loss of consortium.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

FRAUD

97. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

98. As a medical device company, the Alere Defendants had an affirmative continuing duty to warn the public and medical community regarding inefficacy and risks they knew, learned or should have known were associated with their medical devices and products.

99. Defendants knowingly and deliberately falsely marketed the INRatio Products as "accurate," "convenient," "effective," "reliable," "optimal" and "safe" when they knew the INRatio Products were anything but. Meanwhile, Defendants actively concealed and suppressed material facts, namely, that the INRatio Products produced false and erroneous data concerning blood-clotting times, causing consumers to improperly adjust their blood-thinner dosages and increase the risk and likelihood of serious bodily injury and death.

100. Plaintiffs and their respective medical providers who prescribed and/or recommended the INRatio Products, justifiably relied on the reasonable expectation that Defendants would act in compliance with the law, which included disclosing material facts

concerning the false and erroneous data produced by the INRatio Products as well as marketing and promoting the INRatio Products honestly and ethically.

101. Had the true nature of Defendants' INRatio Products been disclosed to Plaintiffs and their respective medical providers, they would not have purchased, recommended for purchase, or sued the INRatio Products, nor would they have relied on them for blood anticoagulation monitoring.

102. Had Defendants disclosed the above material information, that the INRatio Products contained specific defects that produced false and erroneous results, healthcare providers would have been made aware of the defects and would not have prescribed and/or recommended the INRatio Products to consumers, including Plaintiffs. Similarly, Plaintiffs would have been made aware of the defects by consulting with their informed healthcare providers and would not have purchased and/or used the INRatio Products. Further, had Defendants disclosed that the INRatio Products contained specific defects that produced false and erroneous results, Plaintiffs, including those with or without prescriptions, would have been made aware of the defects and would not have purchased and/or used the INRatio Products.

103. Had Defendants more timely removed the INRatio Products from the market (which they eventually did in July 2016), in lieu of downplaying the risks, delaying the public's ability to learn of the defective nature of the devices, and blaming false readings on user error, the defective INRatio Products would not have been available to Plaintiffs for purchase and Plaintiffs could have used other safer alternative devices or methods to properly monitor their INR levels.

104. Defendants knew their concealment and suppression of materials facts was false and misleading, they were fully aware that their promotional and marketing materials contained false and misleading statements, and they were fully aware that the promotional and marketing materials would be relied upon by consumers when deciding to purchase and/or use the INRatio Products.

105. Plaintiffs would not have purchased and/or used the INRatio Products, nor would they have relied on them for blood monitoring, had it not been for Defendants' delay in removing the devices from the market and concealment of material facts and false and misleading statements contained in their promotional materials, marketing materials and packaging.

106. Plaintiffs and their respective medical providers justifiably relied upon Defendants' knowing, affirmative, and active concealment. By concealing material information, Defendants intended to induce medical providers to prescribe INRatio Products and induce patients, such as Plaintiffs, to purchase and/or use the INRatio Products.

107. Defendants also made partial representations while suppressing and actively concealing material facts. Defendants also improperly named and described certain INRatio Products as "INRatio Monitors," leading healthcare professionals and consumers to reasonably believe the INRatio Products allowed users to safely and reliably monitor their INR values. Additionally, in their recall notices, Defendants falsely represented to consumers that the cause of the defective qualities of the INRatio Products was limited to the INRatio2 PT/INR test strips, as well as "certain medical conditions" and the failure to "carefully follow the instructions."

108. Defendants' conduct is malicious, fraudulent, and wanton, and Defendants intentionally mislead and actively concealed material information from consumers in order to increase the sales of the INRatio Products.

109. At all times herein mentioned, the actions of the Defendants, their agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiffs in particular, and to the public generally, in that Defendants did willfully and knowingly promote and continued to sell and distribute the Alere INRatio Products with the specific knowledge that the devices were defective, provided inaccurate INR results and that said defect could seriously and fatally endanger the lives of all patients/users of the Alere

INRatio Products, including Plaintiffs.

110. At all times relevant herein, the Defendants' conduct was malicious, fraudulent, and oppressive toward Plaintiffs in particular and the public generally, and Defendants conducted themselves in a willful, wanton, and reckless manner.

111. The Defendants' aforementioned conduct, misrepresentations and concealment of the above material facts were a substantial factor and a direct, legal and concurrent cause of Plaintiffs' injuries and damages, as described herein.

112. In doing the things aforementioned, the Defendants are guilty of malice, oppression, fraud, and a wanton and willful disregard of persons/patients (such as Plaintiffs) who forseeably might be harmed, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

113. As a direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have been injured in their health, strength and activity, and have suffered, continue to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, disability, physical impairment, inconvenience, grief, anxiety, loss of enjoyment of life, humiliation, and emotional distress, some of which injuries may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

114. As a further direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have lost earnings and earning capacity, and will continue to incur such losses for an indefinite period in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

115. As a further direct and proximate result of the acts and conduct of the Defendants, and each of them, Plaintiffs have incurred medical, hospital and related expenses, and on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

SECOND CAUSE OF ACTION

NEGLIGENCE

116. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

117. As a medical device company, Defendants had an affirmative continuing duty to warn Plaintiffs and/or their medical providers about the dangers associated with the defective Alere INRatio Products, which they knew, or in the exercise of ordinary care should have known, regarding inefficacy and risks associated with their medical device and products.

118. Defendants had a confidential and special relationship with Plaintiffs due to Defendants' vastly superior knowledge of the efficacy and safety risks relating to the Alere INRatio Products.

119. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiffs and Plaintiffs' physicians of the true defects, health risks and lack of efficacy associated with the Alere INRatio Products. Independent of any special relationships of confidence or trust, Defendants had a duty not to conceal the true dangers, defects and risks of the Alere INRatio Products from Plaintiffs and Plaintiffs' medical providers.

120. Misrepresentations made by Defendants about the efficacy and safety of the Alere INRatio Products independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiffs and Plaintiffs' physicians the true risks and defects of the Alere INRatio Products.

121. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiffs and to Plaintiffs' physicians.

122. The following sub-paragraphs summarize, among others, Defendants' breaches of duties and describe categories of acts or omissions constituting breaches of duty by Defendants:

a. Negligently, carelessly and recklessly falsely marketing the INRatio Products as "accurate," "convenient," "effective," "reliable,"

"optimal," and "safe" when they knew the INRatio Products were anything but;

b. Negligently, carelessly and recklessly failing to timely disclose to physicians and patients (including Plaintiffs) that the INRatio Products were defective and provided false INR readings;

c. Negligently, carelessly and recklessly failing to timely disclose that the INRatio Products, including the Monitoring Systems had software glitches and defects that caused the devices to deliver inaccurate INR results to patients and doctors;

d. Negligently, carelessly and recklessly failing to adequately design the INRatio Products;

e. Negligently, carelessly and recklessly failing to adequately research and test the INRatio Products;

f. Negligently, carelessly and recklessly failing to timely disclose to the FDA, the public and physicians, adverse events associated with the INRatio Products;

g. Negligently, carelessly and recklessly failing to ensure that warning notices and recall letters timely reached *all* patients and consumers;

h. Negligently, carelessly and recklessly failing to timely remove the INRatio Products from the market;

i. Negligently, carelessly and recklessly violating applicable state and federal statutes, regulations and guidelines relating to the development, promotion, marketing, testing, and pharmacovigilance of medical devices, including but not limited to the United States Food, Drug & Cosmetic Act and the California Sherman Food, Drug & Cosmetic Act, *including for example:* 21 U.S.C §§ 301 *et seq*; 21 U.S.C §331; 21 U.S.C §333; 21 U.S.C §351; 21 U.S.C §352; 21 U.S.C §360; 21 U.S.C

§360i; 21 U.S.C §360j; 21 C.F.R. §§801 *et. seq;* 21 C.F.R. §801.4; 21 C.F.R. §801.5; 21 C.F.R. §§803 *et. seq.*; 21 C.F.R. §803.50; 21 C.F.R. §§820.1 *et. seq;* 21 C.F.R. §820.3; 21 C.F.R. §820.5; 21 C.F.R. §820.3; 21 C.F.R. §820.198; CAL. HEALTH & SAFETY CODE § 111445; CAL. HEALTH & SAFETY CODE § 111260; CAL. HEALTH & SAFETY CODE § 111295; and CAL. HEALTH & SAFETY CODE § 111300; and

j. Negligently, carelessly and recklessly failing to act as a reasonably prudent device manufacturer and distributor.

123. As a direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have been injured in their health, strength and activity, and have suffered, continue to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, disability, physical impairment, inconvenience, grief, anxiety, loss of enjoyment of life, humiliation, and emotional distress, some of which injuries may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

124. As a further direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have lost earnings and earning capacity, and will continue to incur such losses for an indefinite period in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

125. As a further direct and proximate result of the acts and conduct of the Defendants, and each of them, Plaintiffs have incurred medical, hospital and related expenses, and on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

THIRD CAUSE OF ACTION

NEGLIGENCE PER SE

126. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

127. Defendants violated applicable state and federal statutes, regulations and guidelines relating to the development, promotion, marketing, testing, and pharmacovigilance of medical devices. The federal and state statutes and regulations that Defendants violated include the United States Food, Drug & Cosmetic Act and the California Sherman Food, Drug & Cosmetic Act, *including but not limited to:* 21 U.S.C §§ 301 *et seq*; 21 U.S.C §331; 21 U.S.C §333; 21 U.S.C §351; 21 U.S.C §352; 21 U.S.C §360; 21 U.S.C §360i; 21 U.S.C §360j; 21 C.F.R. §§801 *et. seq;* 21 C.F.R. §801.4; 21 C.F.R. §801.5; 21 C.F.R. §§803 *et. seq*.; 21 C.F.R. §803.50; 21 C.F.R. §§820.1 *et. seq;* 21 C.F.R. §820.3; 21 C.F.R. §820.5; 21 C.F.R. §820.3; 21 C.F.R. §820.198; CAL. HEALTH & SAFETY CODE § 111445; CAL. HEALTH & SAFETY CODE § 111260; CAL. HEALTH & SAFETY CODE § 111295; and CAL. HEALTH & SAFETY CODE § 111300.

128. The Defendants' violation of the above statues, many of which relate to, among other things, the sale, marketing, promotion and pharmacovigilance of medical devices was a substantial factor and a direct, legal and concurrent cause of Plaintiffs' injuries and damages, as described herein.

129. Plaintiffs' injuries resulted from an occurrence the laws and regulations were designed to prevent.

130. Plaintiffs were among the class of persons whom these statutes and regulations were meant to protect.

131. Defendants' violation of these statutes or regulations constitute negligence per se.

FOURTH CAUSE OF ACTION

BREACH OF WARRANTY

132. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

133. Defendants knowingly and deliberately falsely marketed the INRatio Products as "accurate," "convenient," "effective," "reliable," "optimal," and "safe" when they knew the INRatio Products were anything but. Meanwhile, Defendants actively concealed and suppressed material facts, namely, that the INRatio Products produced false and erroneous data concerning blood-clotting times, causing patients to improperly adjust their blood-thinner dosages and increase the risk and likelihood of serious bodily injury and death.

134. Upon information and belief, Plaintiffs and/or their respective medical providers relied upon Defendants' express warranty representations regarding the safety and efficacy of the Alere INRatio Products.

135. The breach of Defendants' warranties was a substantial factor and a direct, legal and concurrent cause of Plaintiffs' injuries and damages, as described herein.

FIFTH CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

136. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

137. At all relevant times herein, Defendants manufactured, distributed, promoted, marketed and/or sold the Alere INRatio Products to Plaintiffs.

138. At all relevant times herein, the Alere INRatio Products did not contain sufficient instructions or warnings concerning defects for reasonable foreseeable uses that were known to Defendants but not recognizable to medical providers and patients.

139. At all relevant times herein, Defendants knew that the Alere INRatio Products was defective, had software issues and provided erroneous INR readings to consumers and that said defects presented a substantial danger to patients. Nevertheless, Defendants failed to provide adequate warnings and knowing that the defects were incurable, failed to timely withdraw the Alere INRatio Products from the market.

140. Plaintiffs would not have purchased the INRatio Products, nor would they have relied on them for blood monitoring, had it not been for Defendants' delay in removing the devices from the market and/or concealment of material facts and false and misleading statements contained in their marketing materials and packaging.

141. Plaintiffs and their respective medical providers justifiably relied upon Defendants' knowing, affirmative, and active concealment. By concealing material information, Defendants induced Plaintiffs' medical providers to prescribe the Alere INRatio Products, and/or induced Plaintiffs into purchasing and using the INRatio Products.

142. The Defendants' aforementioned conduct, misrepresentations and concealment of the above material facts was a substantial factor and a direct, legal and concurrent cause of Plaintiffs' injuries and damages, as described herein.

143. As a direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have been injured in their health, strength and activity, and have suffered, continue to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, disability, physical impairment, inconvenience, grief, anxiety, loss of enjoyment of life, humiliation, and emotional distress, some of which injuries may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

144. As a further direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have lost earnings and earning capacity, and will continue to incur such losses for an indefinite period in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

145. As a further direct and proximate result of the acts and conduct of the Defendants, and each of them, Plaintiffs have incurred medical, hospital and related expenses, and on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

146. In doing the things aforementioned, the Defendants are guilty of malice, oppression, fraud, and a wanton and willful disregard of persons/patients (such as Plaintiffs) who foreseeably might be harmed, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

SIXTH CAUSE OF ACTION

STRICT LIABILITY – MANUFACTURING AND DESIGN DEFECT

147. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

148. At all relevant times herein, Defendants manufactured, distributed, promoted, marketed and/or sold the Alere INRatio Products to Plaintiffs.

149. At all relevant times herein, the Alere INRatio Products contained design and manufacturing defects that were known to Defendants but not recognizable to medical providers and patients. As alleged herein, said defects included, *inter alia*, the Alere INRatio Products failure to provide accurate INR readings to patients and consumers, including Plaintiffs.

150. At all relevant times herein, Defendants knew that the Alere INRatio Products was defective, had software defects, and provided erroneous INR readings to consumers and that said defects presented a substantial danger to patients. Nevertheless, Defendants failed to adequately remedy these defects, and knowing that the defects were incurable, failed to timely withdraw the Alere INRatio Products from the market.

151. Plaintiffs would not have purchased the INRatio Products, nor would they have relied on them for blood monitoring, had it not been for Defendants' delay in removing the devices from the market and/or concealment of material facts and false and misleading statements contained in their marketing materials and packaging.

152. Plaintiffs and their respective medical providers justifiably relied upon Defendants' knowing, affirmative, and active concealment. By concealing material information, Defendants induced Plaintiffs' medical providers to prescribe the Alere

INRatio Products, and/or induced Plaintiffs into purchasing and using the INRatio Products.

153. The Defendants' aforementioned conduct, misrepresentations and concealment of the above material facts was a substantial factor and a direct, legal and concurrent cause of Plaintiffs' injuries and damages, as described herein.

154. As a direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have been injured in their health, strength and activity, and have suffered, continue to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, disability, physical impairment, inconvenience, grief, anxiety, loss of enjoyment of life, humiliation, and emotional distress, some of which injuries may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

155. As a further direct and proximate result of the acts and conduct of the Defendants, Plaintiffs have lost earnings and earning capacity, and will continue to incur such losses for an indefinite period in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

156. As a further direct and proximate result of the acts and conduct of the Defendants, and each of them, Plaintiffs have incurred medical, hospital and related expenses, and on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

SEVENTH CAUSE OF ACTION

VIOLATION OF UNFAIR COMPETITION LAWS

157. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

158. Rhode Island consumer protection law prohibits unfair trade practices. For the reasons described above, Defendants have engaged in unfair or fraudulent business acts or practices in violation of consumer protection laws.

159. Defendants misrepresentations and omissions of material facts, as set forth herein, constitute and unlawful practice because they violate Rhode Island's applicable consumer protection law as well as the Federal Food Drug and Cosmetic Act sections and California Sherman Food Drug and Cosmetic Act sections delineated in the Third Cause of Action (Negligence Per Se), *supra*.

160. Defendants' conduct offends public policy and is immoral, unethical, oppressive, unscrupulous and substantially injurious to consumers. Any justification for Defendants' practices is outweighed by the consequences and harm to Plaintiffs.

161. There were reasonable alternatives available to Defendants to further Defendants' legitimate business interests, other than the conduct described herein.

162. Defendants' conduct was also fraudulent, misleading, or likely to deceive the public.

163. Defendants' misrepresentations and concealment of material facts were made with the knowledge of their effect, and were done to induce Plaintiffs' medical providers to prescribe and Plaintiff to purchase the INRatio Products. Plaintiffs and/or their respective medical providers saw and justifiably relied on Defendants' misrepresentations and concealment of material facts on the marketing and promotional materials, as well as the packaging, when recommending, purchasing or using the INRatio Products.

164. Defendants further violate the consumer protection laws by making partial representations while suppressing and actively concealing material facts. In particular, Defendants represented, in advertisements and promotional materials, that the INRatio Products were "accurate," "convenient," "effective," "reliable," "optimal" and "safe," while failing to disclose to consumers that the INRatio Products produced false and erroneous results. Defendants also improperly named certain INRatio Products "INRatio Monitors," leading healthcare professionals and consumers to reasonably believe the INRatio Products allowed users to safely and reliably monitor their INRs. Additionally, in their recall notices, Defendants falsely represented to consumers that the cause of the defective qualities of the

INRatio Products was limited to the INRatio2 PT/INR test strips, as well as "certain medical conditions" and the failure to "carefully follow the instructions."

165. Defendants' conduct is malicious, fraudulent, and wanton, and Defendants intentionally mislead and actively concealed material information from consumers in order to increase the sales of the INRatio Products.

166. By violating the UCL in the manner described herein, Defendants prevented healthcare professionals and consumers from making informed decisions regarding the use of the INRatio Products, and altered prescribing physicians' decisions concerning their patients' use of the products. Had prescribing physicians known that the INRatio Products produced false and erroneous results, they would not have prescribed the INRatio Products.

167. Plaintiffs would not have purchased and used the INRatio Products had it not been for Defendants' misrepresentations and concealment of material facts. Nor would Plaintiffs have improperly adjusted their blood-thinner dosages based on the results obtained from the INRatio Products, and in doing so, increased the risk and likelihood of serious injury and death. Plaintiffs have suffered injury in fact, and have lost money because of Defendants' fraudulent conduct.

168. Defendants' misrepresentations and omissions alleged herein are objectively material to the reasonable consumer, and they were material to Plaintiffs and their medical providers. Reliance upon the misrepresentations and omissions discussed herein may therefore be presumed as a matter of law. The materiality of such representations and omissions also establishes causation between Defendants' conduct and Plaintiffs' injuries.

169. Defendants have thus engaged in unlawful, unfair, and fraudulent business acts entitling Plaintiffs to remedies as provided by law.

EIGHTH CAUSE OF ACTION

LOSS OF CONSORTIUM

170. Plaintiffs incorporate by reference in this claim for relief each allegation of the preceding paragraphs, with the same force and effect as though fully set forth herein.

171. At all times relevant hereto the Plaintiff's spouse has suffered injuries and losses because of Plaintiff's injuries.

172. For the reasons set forth herein, Plaintiff's spouse has necessarily paid and/or have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as approximate result of Defendants' misconduct.

173. For the reason set forth herein, Plaintiff's spouse has suffered and will continue to suffer damage to and/or the loss of their loved one's support, companionship, services, society and affection.

174. Plaintiff's spouse has suffered great emotional pain and mental anguish.

175. As a direct and proximate result of Defendants' wrongful conduct and failure to comply with applicable standards, Plaintiff's spouse has sustained and will continue to sustain severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs for all general and special damages to which Plaintiff's spouse is entitled by law.

DATED: November 30, 2017

Respectfully submitted,

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

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DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all counts in this Complaint.

DATED: November 30, 2017

Respectfully submitted,

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